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Research Article

Modern Methods of Aphakia Correction with Domestically Produced Intraocular Lens

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Abstract

Rationale: Currently, the primary emphasis in the development of ophthalmic surgery is centred towards the development of high-quality domestic intraocular lens (IOL) models. These models are designed for implantation through a small incision, ensuring precise positioning during suture fixation in the ciliary sulcus. They are characterised by specifically designed shapes and strategically positioned holes in the haptic elements, enabling visual-guided needle manipulation even in instances of miosis or pupil deformation.

Objective: To modernise the design of the domestic model of IOL RSP -1 within the current technical specifications.

Materials and Methods: In collaboration with OOO NEP Eye Microsurgery, we have undertaken a modernisation venture aimed at enhancing the design of the haptic elements of the RSP-1 IOL. This monolithic IOL features plate haptics adorned with precisely crafted holes of specific shapes and sizes.

Suturing with the modernised IOL model was undertaken in eight patients to address intraocular correction of aphakia. The aetiology of aphakia was closed eye trauma of Type A III.

Preoperative visual acuity ranged from 0.01 to 0.7 with aphakic correction, whilst Intraocular pressure ranged from 15 to 20 mmHg.

Suturing this IOL model requires the use of two straight needles interconnected by thread. A puncture is made with a 30G guide needle at a point 2 mm from the limbus within the projection of the ciliary sulcus in the inner segment. Subsequently, through a paracentesis at the 3 o'clock position, the needles are alternately passed beneath the haptic part of the IOL and then withdrawn from the eye at the 9 o'clock position within the projection of the ciliary sulcus. This manoeuvre forms a loop that captures the haptic part of the IOL. Similarly, fixation of the haptic part of the IOL Is achieved in the opposing segment through other V-shaped holes. Repositioning and fixation of the IOL within the projection of the ciliary sulcus is accomplished by pulling the ends of the threads extracted from the eye.

Results: In the postoperative period in all cases, stable IOL position was fixed and IOL was centered. Visual acuity: ranged from 0.2 to 0.9 with correction, whilst Intraocular Pressure (IOP) ranged from 11 to 17 mmHg. The picture obtained by ultrasound biomicroscopy indicates the central position of the IOL.

Conclusion: The proposed modification of IOL RSP -1 with four haptic holes has a number of advantages: import substitution, injector implantation of IOL through a small incision. The shape and location of the holes allow to perform atraumatic and clearly controlled IOL suturing regardless of the pupil diameter. Four-point fixation of the IOL within the ciliary sulcus projection ensures a reliable, stable and anatomically functional position of the IOL. Additionally, the monoblock design serves as a barrier-optical membrane during combined vitreoretinal surgery without obstructing eye fundus visualisation. This IOL model is versatile and suitable for both capsular and extracapsular fixation.

Keywords: *Intraocular Lens; RSP-1; Domestic IOL Model; Guide Needle; Ciliary Sulcus*

Rationale

Despite innovative phacoemulsification technology, in numerous cases, the capsular bag cannot be preserved due to damage to the zonular-capsular apparatus of various origins. Pseudoexfoliative syndrome, occurring in 8.4% to 85.2% of cases, often leads to partial or complete lysis of the ciliary zonule [1-5]. Traumatic damage to the eyeball not only results in the destruction of the crystalline lens and capsular apparatus but can also damage and deform the iris. Concomitant injury of several anatomical structures requires a precise, individualised approach to the selection of the intraocular lens (IOL) model and its subsequent fixation method.

To date, ophthalmic surgery primarily emphasizes the advancement of high-quality domestic consumables and IOL models. Currently, two models of domestic IOLs for aphakia correction are available, manufactured by LLC NEP Eye Microsurgery. In cases where iris pupillary margin and pupil rigidity are preserved, the RSP-3 (Grib) IOL model has demonstrated efficacy, as evidenced by a multitude of studies [6-11]. However, in instances of concurrent lens and iris injury, or when vitreoretinal intervention is necessary, the utility of this IOL model is limited due to challenges in its fixation within the pupil area or the requirement for pharmacological pupil dilation to facilitate a complete examination of the eye fundus during both vitreoretinal intervention and the postoperative period.

In such scenarios, the utilisation of IOLs offering fixation in the ciliary sulcus followed by suturing presents a superior advantage. Nevertheless, upon analysing existing IOL models and suturing techniques, disadvantages and challenges in IOL repositioning emerge. Notably, with two-point fixation, postoperative IOL displacement relative to the axis of fixation zones becomes apparent during suturing. Potential complications may arise, including aberrations in milder instances, anterior chamber irregularities, obstruction of the anterior chamber angle (ACA), and hydrodynamic disturbances in more intricate cases.

Models and suture techniques designed specifically for four-point fixation, thus providing a more stable IOL position, are well proven and widely used [12]. Nonetheless, they also present with several drawbacks. Most lenses have difficult visualization of the haptic holes during surgery that significantly impedes the process of guiding needles for suture fixation. Additionally, in instances of a narrow pupil or deformed pupillary margin, haptic zone holes may be entirely unobservable, necessitating considerable surgical expertise and restricting the pool of specialists capable of performing such operations.

In our opinion, the most controlled technique of IOL fixation involves transscleral ab externo fixation using guide needles and two straight needles connected by thread. This technique was founded by Lewis JS, who, in 1991, advocated for the utilisation of a 28G hollow-bore needle on an insulin syringe as a guide needle, along with straight needles equipped with prolene 10-0 thread, which were tied to the haptic elements of the IOL [13].

The technique of IOL fixation proposed by Canabrava S., *et al*. is currently gaining significant interest. The authors have introduced a method of 4-flange intrascleral IOL fixation using polypropylene 6-0 thread. This technique eliminates the need for creating a scleral flap, suture knots, or glue. Four fixation points are established using a thermocoagulator, securing the flanges above the sclera. This method ensures exceptional stability and centering of the fixed IOL without the reliance of suture knots [12]. However, its worth noting that this fixation method is only applicable for certain imported IOL models, and the wide haptic holes in these models may result in thread displacement relative to the intended fixation point.

Thus, thus there an urgent of IOL model with the possibility of implantation through a small incision providing a clearly controlled position during suture fixation in the ciliary sulcus, having the shape and location of holes in the haptic elements that allow easy needle guidance under visual control even in the cases of narrow or deformed pupil.

Aim of the Study

The objective of this work is to modernize the design of the domestic model of IOL RSP -1 within the current technical specifications.

Materials and Methods

In collaboration with LLC NEP Eye Microsurgery, we modernized the design of haptic elements of IOL RSP-1 which made it possible to use it for the intraocular aphakia correction with the fixation of the lens into the ciliary sulcus.

This model can be used in patients with defects or absence of the lens capsule, with traumatic lens injuries, involutional dystrophy of zonular fibers, and with intraoperative rupture of the posterior capsule during cataract extraction.

The modernized RSP-1 model produced by LLC NEP Eye Microsurgery is a monolithic IOL with plate gaptic with holes. The shape and location of these holes are designed to meet specific requirements, including the ability to guide the needle at any pupil diameter and to facilitate precise, controlled fixation at four points, akin to sewing on a button (Figure 1).

Figure 1: *Modernized RSP-1 model produced by LLL NEP eye microsurgery.*

Suturing of the proposed modernized IOL model was performed in 8 patients for intraocular correction of aphakia. There were five female (62.5%) patients, and three male (37.5%) patients. Patient's ages ranged from 61-84 years (mean age 72.5 years). The cause of aphakia was closed eye trauma type A III [14].

Preop visual acuity ranged from 0.01 to 0.7 with aphakic correction. Intraocular pressure ranged from 15 to 20 mmHg. Secondary glaucoma was diagnosed in five patients. One patient had microinvasive non-penetrating deep sclerectomy (MNDSE). Two patients had micro impulse transscleral cyclophotocoagulation. Two patients had medication correction. The target IOP level was achieved in all the five cases.

Amongst other comorbidities, four patients had lens dislocation into the vitreous cavity; two patients had moderate myopia, one patient had partial optic atrophy, four patients had vitreous herniation, two patients had hemophthalmos, two patients had local retinal detachment, and two patients had traumatic mydriasis. Lens vitrectomy was performed in four cases, and vitrectomy with further IOL implantation and fixation was performed in the remaining four patients.

The method of implanting this IOL model is as follows:

- Firstly, creating the main incision at 12 o'clock. Then, in the outer segment (3 o'clock), a paracentesis is made using an ophthalmic lance tip knife (the area of paracentesis can vary but must be strictly perpendicular to each other). The anterior chamber is filled with viscoelastic.

- IOL implantation is carried out using a cartridge and an injector. In the absence of paralytic mydriasis or aniridia, the IOL can be placed on the iris surface. This placement allows for the suturing process to be fully visible and manageable, minimising intraoperative surgical trauma (Figure 2).
- Moreover, when the IOL is positioned on the iris surface, the holes in the IOL haptics are fully visible. This enables precise marking of the needle guide injection zones, facilitating a clearly controlled and stable fixation of the lens.

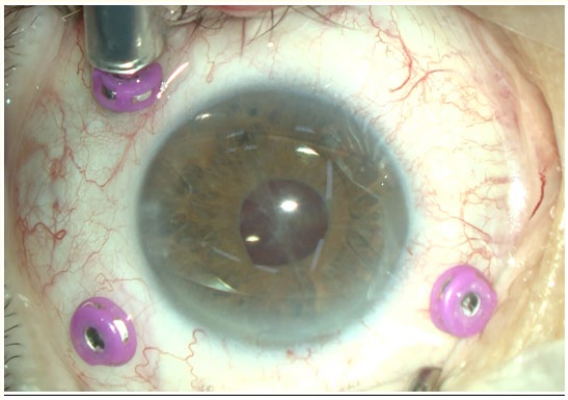

Figure 2: *Stages of IOL RSP-1 fixation: IOL RSP-1 on the iris. Medical mydriasis 4 mm.*

Suturing was performed using two straight needles connected with a thread. In the inner segment (at 9 o'clock) 2 mm from the limbus in the projection of the ciliary sulcus, a puncture was made with a 30G guide needle.

Simultaneously, the shape of the holes serves as a guide for precisely puncturing with the guide needle at the exact location of the holes.

One of the straight needles was introduced into the anterior chamber through the previously formed paracentesis at 3 o'clock passed under IOL haptics in its outer segment. It was inserted into one of the V-shaped holes, and withdrawn from the eye at 9 o'clock at 2 mm from the limbus in the projection of the ciliary sulcus using a 30G insulin needle as a guide.

The elongated shape of the holes facilitates the direct guidance of needles into the pupil area rather than the periphery of the iris. Furthermore, the holes are strategically positioned to align with the most convenient needle passage during suturing. In the successive step, the second straight needle is reintroduced through the paracentesis at 3 o'clock, positioned under the IOL haptics, and inserted into another hole. Subsequently, it is threaded into the lumen of a 30G insulin needle, through which it is withdrawn from the anterior chamber, positioned 2.0 mm away from the site of the initial puncture by the first needle (Figure 3).

At the same time, the loop of the thread formed was capturing IOL haptics at its periphery. The haptic part was similarly fixed in its inner segment through the second V-shaped holes (Figure 3). By pulling the ends of the threads taken out of the eye, the IOL was repositioned behind the iris to the anatomically correct position in the pupil area; And the loop was fixing the haptic part in the outer and inner segments of the eye in the ciliary sulcus area (Figure 4).

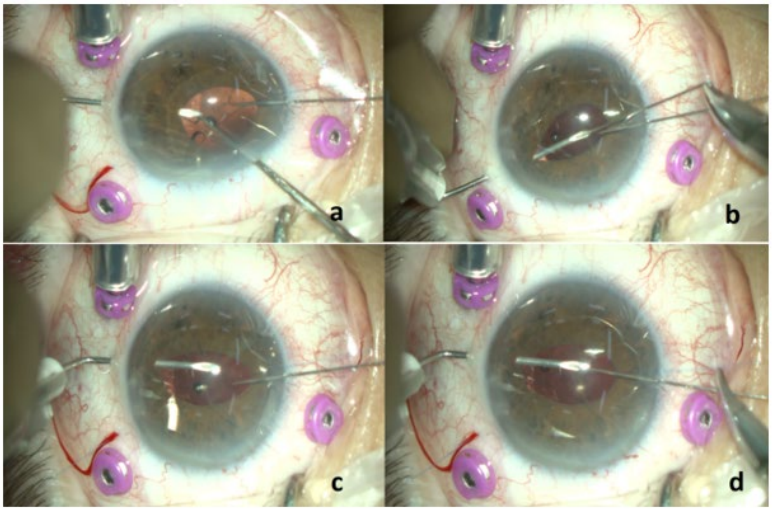

Figure 3: *Stages of IOL RSP-1 fixation.*

A: The 30G guide needle passes beneath the IOL haptics into one of the V-shaped holes. A hook helps rotate the IOL, allowing the guide needle to pass freely through the haptic hole.

B: A straight threaded needle is secured in the hole of the 30G insulin needle.

C: The second straight threaded needle is inserted through the paracentesis. In the opposite segment, a 30G guide needle is inserted to meet it, and then passed through the paired haptic hole.

D: The threaded needle is fixed in the hole of the 30G insulin needle and passed under the IOL haptics.

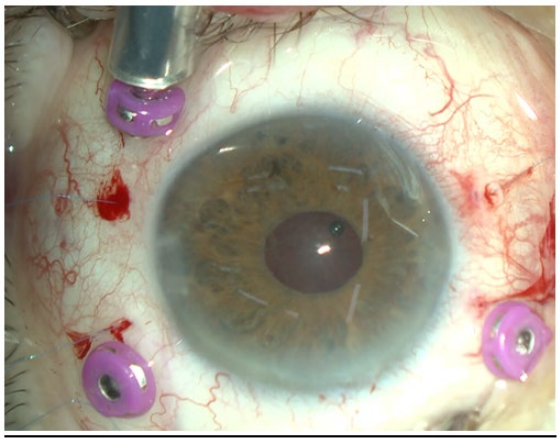

Figure 4: *Stages of IOL RSP-1 fixation.*

The haptic elements are grasped by the thread loop and fixed in the projection of the ciliary sulcus. The IOL is centered.

The ends of the threads that were taken out can be fixed in the sclera with a Z-shaped suture, using flanges or interrupted suture at surgeon's discretion.

Results

In the postoperative period, stable IOL position was recorded in all the cases, the IOL was centered. Visual acuity ranged from 0.2 to 0.9 with correction. IOP ranged from 11 to 17 mmHg.

Ultrasound biomicroscopy (UBM) confirmed central placement of the intraocular lens (IOL) and no effect on the ciliary body region (Figure 5).

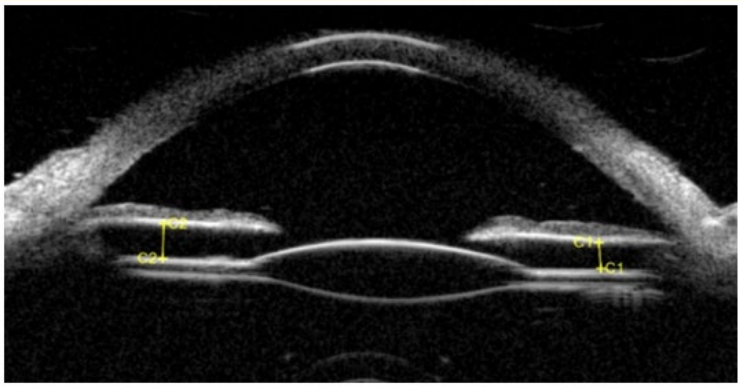

Figure 5: *UBM picture. IOL is fixed in the project of the ciliary sulcus.*

The benefits of implanting a domestically modernised IOL model with suture fixation in the ciliary sulcus projection using the developed technique is validated by the clinical cases presented below.

Example 1

Patient B. 67 years old, admitted to S. Fedorov Eye Microsurgery Federal State Institution.

Presenting diagnosis: OD Aphakia. Dislocation of native lens into the vitreal cavity. Secondary compensated glaucoma operated by laser.

Medical history: In March 2023, OD closed eye trauma type A III.

On admission: Visus OD - 0.02 sph+11.5 cyl -0.75 ax 160 = 0.15; IOP 20 mmHg. At biomicroscopy OD Aphakia.

Surgical treatment was performed; OD Vitrectomy + PFOS (removed)+ lensectomy + IOL implantation with suturing in the ciliary sulcus (Figure 6 and 7).

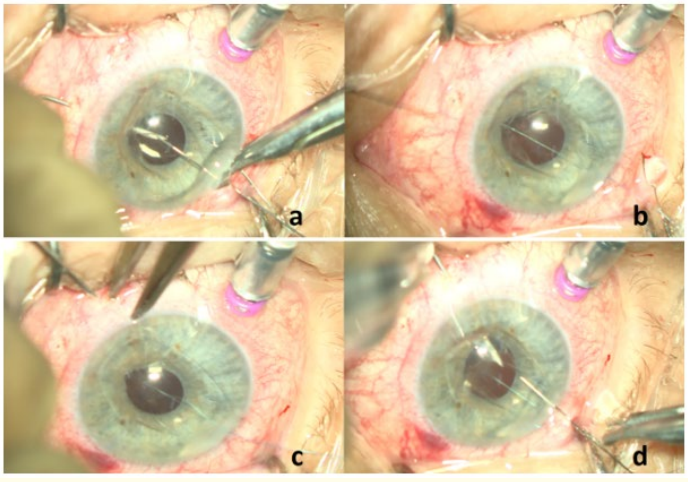

Figure 6: *Patient B. Stages of the IOL RSP-1 fixation (fixation in the low segment):*

A: A straight threaded needle is inserted through the paracentesis into one of the V-shaped holes and secured within the lumen of the 30G guide needle.

B: A threaded needle is withdrawn at the 7 o'clock position within the projection of the ciliary sulcus zone.

C: The second puncture is made 2 mm from the limbus using a 30G insulin needle.

D: Another straight threaded needle is passed through the paracentesis into another V-shaped hole and anchored within the lumen of the 30G insulin needle. Consequently, the haptic element is captured by the loop of the thread.

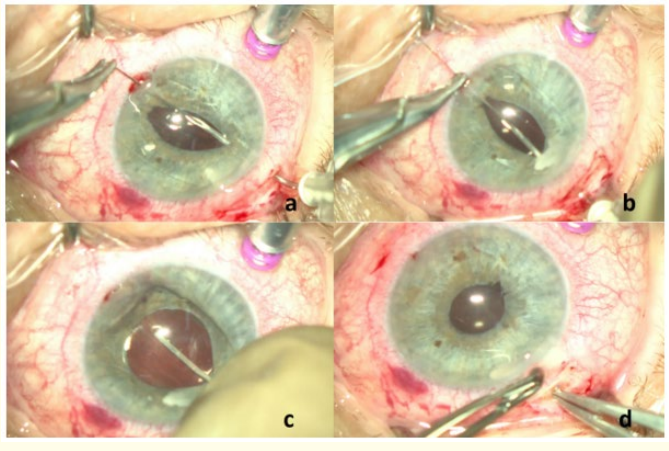

Figure 7: *Patient B. Stages of the IOL RSP-1 fixation (fixation in the upper segment):*

A: A straight threaded needle is inserted through the paracentesis into a V-shaped hole within the projection of the ciliary sulcus zone.

B: The second straight threaded needle is inserted through the paracentesis into another V-shaped hole and anchored within the lumen of the 30G insulin needle. The haptic element is then secured by the loop of the thread.

C: The IOL is immersed in the posterior chamber of the eye by a spatula.

D: The IOL is centred and secured within the projection of the ciliary sulcus with flanges.

Postoperative period (Day 1)

- Visual acuity (VA) OD: 0.4; Intraocular pressure (IOP): 12 mm Hg.

Postoperative period (day 7)

- Visual acuity (VA): 0.7 uncorrected (n/c); IOP: 11 mm Hg.
- Status oculi (St. ocul.): OD Cornea is transparent; anterior chamber depth is medium; moisture is clear. The pupil is rounded, with attenuated photoreaction.
- The IOL was correctly positioned with suture fixation in the ciliary sulcus at 1 o'clock and 7 o'clock (Figure 8).
- Ocular fundus reflex was pink. The membranes are adherent.

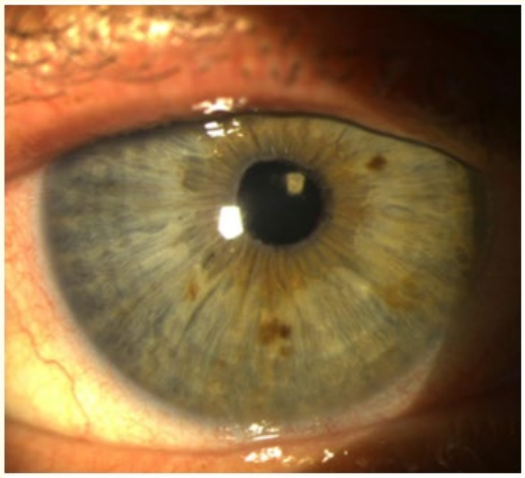

Figure 8: *Patient B. Seventh day post operation. OD IOL is in the correct position, centered, fixed in the ciliary sulcus projection at 1 and 7 o'clock.*

Discussion

Currently, the selection of optimal IOL models for correcting aphakia remain an ongoing challenge. Existing IOL models used for suturing have several disadvantages; Manipulating the IOL during suturing is difficult, especially when haptic holes are located peripherally and cannot be visualised under insufficient mydriasis. There is also a lack of specialised IOL models and techniques for suturing. Furthermore, numerous IOL suturing techniques used today present a variety of challenges.

Fixating IOLs to the iris often results in deformities in pupil shape and function, pigment dispersion, iris atrophy, pigmentary glaucoma, cystic macular oedema, and there can be a high risk of inflammatory reactions in the postoperative period due to constant trauma to the iris tissue by threads and haptics [15]. Pupillary fixation of IOLs can lead to iris atrophy, pigment dispersion, ophthalmic hypertension, and inflammatory reactions [16]. Anterior chamber fixation of IOLs can trigger epithelial-endothelial dystrophy due to endothelial cell loss, synechiae formation, fibrotic changes in the trabecular zone, and ocular hypertension [17,18]. Contact between the IOL and iris pigment layer may provoke secondary pigmentary glaucoma and inflammatory processes [17,18].

Whilst a new surgical technique of IOL transscleral fixation without sutures has gained popularity, thereby offering advantages such as achieving the optimal physiological positioning of the IOL and avoiding contact with the ciliary body, it presents with its own set of challenges. These challenges include a steep learning curve and risks of haptic element damage, lens tilt, protrusion of hard haptic elements, and the occurrence of endophthalmitis [15,19,20]. This technique is applicable only to three-piece IOL models.

In our view, the most atraumatic and controlled technique involves scleral fixation using straight or curved needles and guide needles [22,23]. This technique is utilised for suturing dislocated IOLs [21] and for fixation during implantation into aphakic eyes.

It's essential to emphasise the importance of domestic manufacturers paying closer attention to meeting numerous requirements for IOL technical parameters. In case of IOL implantation with subsequent suture fixation in the ciliary sulcus and high expectations regarding patients' postoperative optical result, the level of requirements to IOL models increases. When developing the parameters for the modernization of the proposed IOL model, we were guided by the following requirements - IOL fixation in four points in order to ensure stable IOL position in the postoperative period; location and shape of the holes in the haptics maximizing the possibility of manipulation regardless of the pupil diameter. This assists visualisation and allows for precise needle guidance, even in cases of narrow pupils measuring 3 - 4 mm [22,23].

Conclusion

As of now, the search for a universal model of domestic IOL, possessing undeniable advantages over existing imported IOLs as well as capable of delivering high anatomical and functional outcomes, persists.

The proposed modification of IOL RSP-1 with four haptic holes has a number of advantages - import replacement, injection IOL implantation through a small incision. The strategic shape and placement of these holes ensure atraumatic and meticulously controlled IOL implantation, independent of pupil diameter. Moreover, the four-point fixation within the ciliary sulcus guarantees a dependable, dedicated, and anatomo-functional positioning of the IOL. In scenarios involving combined vitreoretinal surgery, the monoblock designs acts as a barrier-optical membrane, preserving unhindered visualisation of the eye fundus. Furthermore, this IOL model is versatile, catering to both capsular and extracapsular fixation requirements.

Author's Contributions

Kislytsyna NM: Development of the research concept and design, performing surgical procedures and the analysis of the obtained data.

Sultanova DM: Assisting in surgical procedures, recording research results and data editing.

Novikov SV: Development of the research concept and design and the improvement of research materials.

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